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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,445	05/23/2006	Jonathan Hughes	BT/3-22348/A/PCT	4198

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EXAMINER	
AFREMOVA, VERA	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
09/08/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/580,445	HUGHES ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) *2,5 and 9-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/28/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election of the group I, claims 1, 3, 4 and 6-8, in the reply filed on 6/02/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2, 5 and 9-11 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected invention(s), there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 6/02/2008.

Claims 1, 3, 4 and 6-8 are under examination in the instant office action.

Specification

The disclosure is objected to because of the following informalities:

1. As provided in 37 CFR 1.77(b), the specification of a utility application should include the particular sections in order with the section heading.

2. The current address of the depository collection is missing (page 8).

Appropriate correction(s) are required.

Claim Objections

Claims 1, 3, 4 and 6-8 are objected to because of the following informalities:

The Latin name of microorganisms should be italicized.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

Indefinite

Claims 1, 3, 4 and 6-8 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the use of nitrile hydratase "obtainable from a microorganism of the Dietzia genus". It is uncertain whether the claimed invention encompasses the use of a pure enzyme or some crude preparation in a form of microbial cells as intended for claim 6. The distinguishable properties of a pure enzyme nitrile hydratase "obtainable from a microorganism of the Dietzia genus" are uncertain in the light of specification. Although claim 6 appears to encompass the use of microbial cells for treatment of nitrile, it does not explicitly recite the final form of enzyme to be used in the method. Therefore, being dependent of indefinite claim 1, the instant claim 6 appears to encompass that enzyme is obtained or extracted from the cells. It is suggested to amend claim 1 with the limitation of claim 6 as disclosed in the specification.

Claims 3 and 4 contains parenthesis and, thus, it is uncertain if the term in parenthesis is alternative meaning, additional limitation or else.

Deposit

Claim 8 is rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific microorganism *Dietzia natronolimnaious* NCIMB 41165. Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not clear from the specification or record that the microorganism is readily available to the public.

The objection and accompanying rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because NCIMB has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Please, also provide deposit receipt of the claimed strain for the record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 4, 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamada et al. (IDS reference; Biosci. Biotech. Biochem., 1996, 60(9):1391-1400).

Claims are directed to a method for producing ethylenicaly unsaturated amide wherein the method comprises one active step of treating a nitrile with a nitrile hydratase enzyme in an aqueous medium. The nitrile hydratase enzyme is derived from microorganism belonging to *Dietzia* including *Dietzia sp., Dietzia maris*, and *Dietzia natronolimnaious* strain NCIMB 41165.

Yamada et al. discloses a method for producing ethylenicaly unsaturated amide including acrylamide wherein the method comprises one active step of treating a nitrile or acrylonitrile with a purified nitrile hydratase enzyme in an aqueous medium (entire document including Fig. 4). The nitrile hydratase enzymes are purified or derived from various microorganisms. Although the cited nzymes are not extracted from the cells belonging to *Dietzia* including *Dietzia sp., Dietzia maris* and/or *Dietzia natronolimnaious* strain NCIMB 41165, the properties of the enzyme as intended for the claimed invention are not described in the as-filed specification and,

thus, the differences, if any, cannot be established. Thus, the cited method comprising step of treating a nitrile with a purified nitrile hydratase in an aqueous medium is identical to the claimed method within the meaning of the claims and when read in the light of specification.

Claims 1, 3, 4, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,562,603 (Bramucci et al) or by US 6,916,638(Aoki et al).

Claims are directed to a method for producing ethylenicaly unsaturated amide wherein the method comprises one active step of treating a generic nitrile with a nitrile hydratase enzyme in an aqueous medium wherein the nitrile hydratase enzyme is in a form of whole microbial cells belonging to *Dietzia* including *Dietzia sp.* and/or *Dietzia maris*.

US 6,562,603 (Bramucci et al) discloses a method for producing ethylenicaly unsaturated amide wherein the method comprises one active step of treating a nitrile with a nitrile hydratase enzyme in an aqueous medium wherein the nitrile hydratase enzyme is in a form of whole microbial cells belonging to *Dietzia sp.* For example: see entire document, especially, col.18, lines 11-26.

US 6,916,638(Aoki et al) discloses (see entire document, especially, col. 36, example 6) a method for producing amide wherein the method comprises one active step of treating a "nitrile" or glycinonitrile with a nitrile hydratase enzyme in an aqueous medium wherein the nitrile hydratase enzyme is in a form of whole microbial cells belonging to *Rhodococcus maris* or *Dietzia maris* (same microorganisms in light of Rainey et al, see title, for example.).

The cited references are considered to anticipate the claimed method because they disclose methods that comprise one identical active step of treating a generic nitrile with generic cells of the same microbial genus or species as required by the presently claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamada et al. (IDS reference; Biosci. Biotech. Biochem., 1996, 60(9):1391-1400), Nagasawa et al. (IDS reference; Pure and Appl. Chem. 1995, 67(7):1241-1256), US 6,562,603 (Bramucci et al) and US 6,916,638(Aoki et al).

Claims are directed to a method for producing ethylenically unsaturated amide wherein the method comprises one active step of treating a nitrile with a nitrile hydratase enzyme preparation in an aqueous medium wherein the nitrile hydratase enzyme preparation is either purified enzyme or cells of microorganisms belonging to *Dietzia.* Some claims are further drawn to the use of microorganisms belonging to *Dietzia sp., Dietzia maris*, and/or *Dietzia natronolimnaious* strain NCIMB 41165.

The references by Yamada et al. (see above) and by Nagasawa et al. (entire document including pages 1244-1248) teach microbial production of chemicals and disclose methods for production of ethylenically unsaturated amides by converting the corresponding acrilonitrile or

"(meth)acrylonitrile" with microbial enzymes having nitrile hydratase activity wherein the methods encompass either the use of pure enzyme catalysts or the use of microbial cells belonging to various genera and species. The cited references are silent about enzymatic activity of *Dietzia.*

However, the cited patents US 6,562,603(Bramucci et al) and US 6,916,638 (Aoki et al) (as explained above) demonstrate that the cells of microorganisms belonging to *Dietzia* including *Dietzia sp.* and/or *Dietzia maris* have nitrile hydratase activity and are used for conversion of nitriles to corresponding amides.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to substitute enzymes or cells with nitrile hydratase activity obtained from the cultures of *Dietzia* including *Dietzia sp.* and/or *Dietzia maris* of US 6,562,603(Bramucci et al) and US 6,916,638 (Aoki et al) for the enzymes or cells with nitrile hydratase activity in the methods of Yamada et al. and/or by Nagasawa et al. with a reasonable expectation of success in producing ethylenically unsaturated amides because methods for producing ethylenically unsaturated amides with microbial nitrile hydratases have been know and practiced and because cultures of *Dietzia* have been known and used for their nitrile hydratase activity for the same purpose of converting nitriles into amides as adequately demonstrated by the cited references.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

With respect to the claim 8 it is noted that even if the cells of the strain NCIMB 41165 have not been available in the prior art, the use of a nitrile hydratase purified from other

microbial cells would have been obvious to one of skill in the art within the meaning of 35 USC § 103.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

August 28, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657